# PATENT COOPERATION TREATY

# PCT



# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference<br>P06922PC00 | **FOR FURTHER ACTION** | See Form PCT/IPEA/416 |
|---|---|---|
| International application No.<br>PCT/SE2004/001577 | International filing date *(day/month/year)*<br>29.10.2004 | Priority date *(day/month/year)*<br>29.10.2003 |
| International Patent Classification (IPC) or national classification and IPC<br>A61K6/06 | | |
| Applicant<br>DOXA AB et al. | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 5 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

| | | |
|---|---|---|
| ☒ | Box No. I | Basis of the opinion |
| ☐ | Box No. II | Priority |
| ☒ | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| ☒ | Box No. IV | Lack of unity of invention |
| ☒ | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| ☐ | Box No. VI | Certain documents cited |
| ☐ | Box No. VII | Certain defects in the international application |
| ☒ | Box No. VIII | Certain observations on the international application |

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 13.04.2005 | 06.02.2006 |
| Name and mailing address of the international preliminary examining authority:<br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465 | Authorized Officer<br>Paloniemi Legland, R<br>Telephone No. +49 89 2399-7315 |

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/SE2004/001577

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   **Description, Pages**

   1-17 as originally filed

   **Claims, Numbers**

   1-27 filed with the demand

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 27

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 27

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

| | | |
|---|---|---|
| the written form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |
| the computer readable form | ☐ | has not been furnished |
| | ☐ | does not comply with the standard |

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

## Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
   - ☐ restricted the claims.
   - ☒ paid additional fees.
   - ☐ paid additional fees under protest.
   - ☐ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☐ not complied with for the following reasons:

4. Consequently, this report has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-26 .

## Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Yes: | Claims | 1,11 |
| | No: | Claims | 21-23 |
| Inventive step (IS) | Yes: | Claims | 1,11 |
| | No: | Claims | 21-23 |
| Industrial applicability (IA) | Yes: | Claims | 1-26 |
| | No: | Claims | |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

## Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item I**
**Basis of the report**

The amendments filed with the demand fulfil the requirements of Art. 34 PCT.

**Re Item III**
**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

No opinion concerning the novelty, inventive step and industrial applicability of claim 27 has been made since there is no search report established for said claim.

**Re Item IV**
**Lack of unity of invention**

The examination has been made on the basis of the claims 1-26. The objections concerning the lack of unity of claims 1-10 and 21-26 on one hand and claims 11-20 on the other hand have been overcome by the amendments filed with the demand.

**Re Item V**
**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: WO 03 082765 A1
D2: GB-A-1 497 022
D3: US-A-5 063 257

The present claim 1 is directed to a system for chemically bonded material, comprising an aqueous hydration liquid, a powdered material (comprising a first and a second binder phase), a reactive glass and a second portion of aqueous hydration liquid. The rest of the features present in said claim are not clear (see **VIII**).
Claim 11 is directed to a powdered material for dental or orthopaedic applications comprising a cement system, a second, non-ceramic binder phase, a reactive glass, said second binder phase comprising a polycarboxylic acid. The rest of the features of

claim 11 are unclear (see **VIII**).
Claim 21 is directed to an aqueous hydration liquid comprising a cement system and a non-ceramic binder phase. The rest of the features of claim 21 are unclear (see **VIII**). In the present form of claim 21 it seems that document D2 is highly relevant for the novelty of said claim (p.1, l.50-58).
It seems that the essential features of the present invention are the calcium aluminate/silicate (=cement), the reactive glass, the polyacrylic acid and inert fillers (dental glass). None of the documents cited on the search report disclose said features. Documents D1-D2 do not disclose reactive glass and document D3 does not disclose Ca-aluminate or Ca-silicate.
Concerning inventive step none of the cited documents deal with the problem of providing chemically bonded ceramic (CMC) materials with a combination of improved initial and final properties. Thus, an inventive step may be acknowledged.

**Re Item VIII**
**Certain observations on the international application**

Claims 1-8, 10, 11, 21 and 26 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved, which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

The relative terms "low" and "less stable" used in claim 19 and terms "a part" and "most" used in claims 15 and 23 have no well-recognised meaning and leave the reader in doubt as to the meaning of the technical features to which they refer, thereby rendering the definition of the subject-matter of said claim unclear, Article 6 PCT.

CLAIMS (Amended under A. 34 PCT 08.04.2005)

1. A system for a chemically bonded material, comprising
an aqueous hydration liquid;
a powdered material comprising a first binder phase (c), which powdered material has the capacity following saturation with the liquid reacting with said first binder phase to hydrate to a chemically bonded ceramic material;
a second, non-ceramic binder phase having a different initiation time for setting and/or a different setting rate than the initiation time for hydration and the hydration rate, respectively, of said first binder phase,
characterised in that the system further comprises
a reactive glass; and
a second portion of aqueous hydration liquid ($w_{GIC}$),
wherein
$w = w_c + w_{GIC}$
$(w_c/c)$ + (second binder phase)/(reactive glass) + $w_{GIC}$/(reactive glass)

with $0.2 < w_c/c < 0.45$, 0 < (second binder phase)/(reactive glass) < 0.21 and $0.2 < w_{GIC}$/(reactive glass) < 0.45.

and in that the system provides for an ionic interaction between the hydration reactions and setting reactions of the first binder phase (c ) and the second binder phase, respectively.

2. A system according to claim 1, characterised in that it is adapted to enable an initial pH to be kept < 7, more preferably < 4 and most preferably 1-3 to control properties related to different initiation time for setting and hardening of the part systems.

3. A system according to any one of claims 1-2, characterised in that the second binder phase comprises a polycarboxylic acid and/or a copolymer or a salt or an ester thereof providing a pH value in the system of < 7, preferably <4 for the first 20 minutes after mixing, preferably, a pH in the interval 1-4 for the first 10 minutes, and most preferably for the first 5 minutes.

4. A system according to any one of claims 1-2, characterised in that a base is comprised in the system, so as to achieve a change of the pH to a pH > 7, more preferably a pH > 10, after an initial period of time after mixing of the system of a few minutes up to approximately 5 minutes at pH < 7.

5. A system according to any one of claims 1-3, characterised in that an additional acid is comprised in the system, so as to keep the pH < 7 during a prolonged time of up to 30 minutes, preferably up to 20 minutes.

6. A system according to claim 4 or 5, characterised in that the system comprises a porous material, preferably a nano/meso-pore structure or a zeolite type structure, that is able to release said base or acid, respectively.

7. A system according to claim 4 or 5, characterised in that particles of said first binder phase are coated with a dissolution-reducing layer, preferably comprising a glyconate.

8. A system according to any one of the preceding claims, characterised in that it comprises inert filler particles composed of pre-hydrated chemically bonded ceramics, preferably of the same composition as said first binder phase.

9. A system according to any one of the preceding claims, characterised in that it comprises semihydrate of $CaSO_4$ and/or a combination of phosphoric acid and zinc oxide-forming Zn-phosphate.

10. A system according to any one of the preceding claims, characterised in that the system yields an initial strength above 5 MPa measured by diametral tensile strength after 15 minutes.

11. A powdered material for dental or orthopaedic applications for use in the system of claim 1, comprising a first binder phase essentially consisting of a cement system, which powdered material has the capacity following saturation with a hydration liquid reacting with said first binder phase to hydrate to a chemically bonded ceramic material, and an additive of a second, non-ceramic

binder phase having a different initiation time for setting and/or a different setting rate than the initiation time for hydration and the hydration rate, respectively, of said first binder phase, characterised in that the powdered material comprises a reactive glass and that the second binder phase comprises a polycarboxylic acid or a copolymer or a salt or an ester thereof having a molecular weight of 100–250,000, preferably 1000–100,000, in an amount of up to 30 % by weight, based on the powdered material including any dry additives.

12. A powdered material for dental applications of claim 11, characterised in that the polycarboxylic acid or a copolymer or a salt or an ester thereof, is present in an amount of 1-20 %, and preferably 3-15 % by weight, based on the powdered material including any dry additives.

13. A powdered material for orthopaedic applications of claim 11, characterised in that the polycarboxylic acid or a copolymer or a salt or an ester thereof is present in an amount of 1-15 % and preferably 2-5 % by weight, based on the powdered material including any dry additives.

14. A powdered material of any one of the claim 11-13, characterised in that the chemically bonded ceramic material is a material in the group that consists of aluminates, silicates, phosphates, sulphates and combinations thereof, preferably having cations in the group that consists of Ca, Sr and Ba, calcium aluminate cements being most preferred, in which case the first binder phase preferably has a composition between the phases $3CaO \bullet Al_2O_3$ and $CaO \bullet 2Al_2O_3$, most preferably about $12CaO \bullet 7Al_2O_3$, optionally as glass phases.

15. A powdered material according to any one of the claim 11-14, characterised in that at least a part or most preferred all the reactive groups of said polycarboxylic acid or salt thereof bond to the chemically bonded ceramic material.

16. A powdered material according to any one of the claim 11-15, characterised in that said polycarboxylic acid or copolymer or salt or ester thereof is a substance in the group that consists of poly acrylic acid,

poly(acrylic-co-maleic acid), poly(itaconic acid), tricarballylic acid; copolymers, salts and esters thereof; and combinations thereof.

17. A powdered material according to any one of any one of the claim 11-16, characterised in that it contains an inert phase additive, preferably including dental glass and preferably at a content of 3-30 weight-% more preferably 5-20 %.

18. A powdered material according to claim 17, characterised in that said inert phase additive has a particle size of 0.1-5 μm, more preferably 0.2–2 μm, and most preferably 0.3-0.7 μm.

19. A powdered material according to claim 17 or 18, characterised in that said inert phase comprises low amounts of less stable phases or reactive phases including glasses, preferably below 10 % of the inert phase content, which less stable phases or reactive phases preferably comprise fluoride and/or phosphorus.

20. A powdered material according to any one of claims 11 to 19, characterised in that it has the form of granules, preferably of a size below 1 mm, more preferred below 0.5 mm and most preferred below 0.4 mm and having a granule compaction density above 35 %, preferably above 50 % most preferred above 60%.

21. An aqueous hydration liquid for a powdered material comprising a first binder phase essentially consisting of a cement system, which powdered material has the capacity following saturation with the hydration liquid reacting with said first binder phase to hydrate to a chemically bonded ceramic material, characterised in that said hydration liquid comprises an additive of a second, non-ceramic binder phase, which second binder phase has a different initiation time for setting and/or a different setting rate than the initiation time for hydration and the hydration rate, respectively, of said first binder phase, and in that the hydration liquid together with the powdered material provides for an ion interaction between the hydration reactions and setting reactions of the first

binder phase and the second binder phase, respectively.

22. An aqueous hydration liquid according to claim 21, characterised in that said second binder phase comprises a polycarboxylic acid or a copolymer or a salt or an ester thereof.

23. An aqueous hydration liquid according to claim 22, characterised in that at least a part or most preferred all of the reactive groups of said polycarboxylic acid or salt thereof bond to the chemically bonded ceramic material.

24. An aqueous hydration liquid according to claim 22 or 23, characterised in that said polycarboxylic acid or copolymer or salt or ester thereof is a substance in the group that consists of poly acrylic acid, poly(acrylic-co-maleic acid), poly(itaconic acid), tricarballylic acid; copolymers, salts and esters thereof; and combinations thereof.

25. An aqueous hydration liquid according to any one of claims 22-24, characterised in that said polycarboxylic acid or copolymer or salt or ester thereof has a molecular weight of 100–250,000, preferably 1000–100,000.

26. An aqueous hydration liquid according to any one of claims 21-25, characterised in that it has a pH of 1-7, preferably > 3, before the hydration and setting reactions.

27. A chemically bonded material formed from the system of claim 1, the binder phase of which essentially consists of an inorganic cement phase and which material is *in situ* formed on a substrate or in a cavity, characterised in that said material also comprises a reactive, soluble glass, an *in situ* formed phase of polyacrylate polymer or co-polymer.